K022192

JAN 2 4 2003

Summary of Safety and Effectiveness

Date of Preparation: July 1, 2002

Submitter: SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887

Contact: Paul L. Kittinger
Telephone: 714-283-2228

Device Trade Name: **Pegasus™ Nasal CPAP System**

Device Common/Classification Name: The Pegasus™ Nasal CPAP System is a SensorMedics Corporation device classified under 73 BZD, "Non-Continuous Ventilator, per Regulation No. 868.5905.

Predicate Devices: The Bird Products Corporation Orion, the Resprionics Remstar Pro, and the Resmed S6 Elite Nasal CPAP Systems.

Intended Use: The Pegasus™ Nasal CPAP System is intended for treatment of Adult Obstructive Sleep Apnea (OSA). Obstructive Sleep Apnea is defined as the absence of air movement in ten seconds during sleep. Obstructive Sleep Apnea is usually diagnosed through a sleep study. The study obtains the optimum level of pressure required to maintain airway pressure to the obstructed airway. The positive pressure allows the airway to stay open. The Pegasus™ Nasal CPAP System is intended only for spontaneously breathing patients.

Device Description: The Pegasus™ Nasal CPAP System is intended to provide a regulated and continuous positive airway pressure for the treatment of adult individuals suffering from obstructive sleep apnea (OSA). The positive pressure is clinician-adjustable within the designed operating range, as is enabling of the bar graph pressure indicator mode. User controls are On/Off switch, selecting the physician-enabled bar graph, viewing the real-time clock and setting of the real-time clock. The Pegasus™ is designed to be used with a 22-millimeter, smooth-bore air delivery hose and user- or physician-selected nasal or face mask. The Pegasus™ consists of a plastic enclosure that surrounds a power supply, impeller and motor, microprocessor, motor controller, display and switch inputs.

Input Power Supply: 90-260 VAC, 50-6- Hz
Motor & Impeller: Papst 24-VDC brushless motor
Microprocessor: 16-bit Microchip microcontroller with 16K of program space, 1536 bytes of RAM, 256 bytes of eeprom and running at 4.0 mHz.
Motor Controller: Motorola MC33035 controller for brushless D.C. motor, operating from 10 to 30 Vdc.
Pressure Readout Display: 4-digit, 7-segment display controlled by the microprocessor. The digits are multiplexed so that only one digit is on at a time. The 4-digits provide a quantitative, numerical readout of the delivered pressure, and their vertical segments provide and indicator-type bar graph display of the delivered pressure.

Switch Inputs: There are 6 membrane push-button switches used for input of Mode, Plus and Minus pressure, Rise to Pressure On, Rise to Pressure Off And Real-time Clock for compliance.

Titration: Remote access via RS-232 port for setting or changing Titration.

Comparison to Predicate Devices: The Pegasus™ Nasal CPAP System is primarily similar to the Bird Orion Nasal CPAP System [510(k) No. K020730], but incorporates improved regulation of the delivered pressure as in two other devices, the Resprionics Remstar Pro [current version of the Aria LX, 510(k) No. K993307] and the Resmed S6 Elite [current version of the Sullivan III, 510(k) No. K930656].

Summary of Performance Testing: Performance testing was conducted in the laboratory to confirm compliance to device specifications; all functions were verified to operate as designed and intended, and measured parameters met required ranges and accuracies. Testing to internationally accepted standards for electrical safety and electro-magnetic compatibility were performed by a Nationally Recognized Testing Laboratory (NRTL); the Pegasus complied with the requirements of these standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

Mr. Paul Kittinger
Manager, Regulatory Affairs
SenorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K022192
Trade/Device Name: Pegasus™ Nasal CPAP System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: October 28, 2002
Received: October 29, 2002

Dear Mr. Kittinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022192

Device Name: **Pegasus™ Nasal CPAP System**

Indications For Use:

The Pegasus™ Nasal CPAP System is intended for treatment of Adult Obstructive Sleep Apnea (OSA). The Pegasus™ Nasal CPAP System is intended only for spontaneously breathing patients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022192

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)